K010369
1 of 5

MAY - 8 2001

4/27/01

Summary of Safety and Effectiveness Information	ORTHOTEC, LLC.
Premarket Notification, Section 510(k)	APRIL 27, 2001

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**
   Trade Name: [redacted] **Claris Plate System**
   Common Name(s): pedicle screw, vertebral screw
   Classification Name(s): Pedicle Screw Spinal System (Class II uses)

2. **Establishment Name & Registration Number:**

   Name: ORTHOTEC, LLC.
   Number: 2031734

3. **Classification(s):**

   § 888.3060 – Spinal Intervertebral Body Fixation Orthosis
   § 888.3070 – Spondylolisthesis Spinal Fixation Device System
   § 888.3070 – Pedicle Screw Spinal System (Class II Uses)

   Device Class: Class II for the requested indications
   Classification Panel: Orthopaedic and Rehabilitation Devices Panel
   Product Code(s): KWP, MNH, MNI respectively

4. **Indications for Use:**

The Claris Plate System is a posterior, non pedicle system of the non cervical spine is indicated for patients with degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies,spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis) tumors, failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine (T1-Sacrum) fixation only.

In addition, the Claris Plate System is a posterior pedicle system indicated for the treatment of patients having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint in skeletally mature patients receiving fusion using autogenous bone graft only having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum) and intended to be removed after the development of a solid fusion mass.

Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, failed previous fusion (pseudarthrosis)

4. Substantial Equivalence:

Basis of substantial equivalence:
The SCS Claris Plate System is substantially equivalent to AcroMed's titanium VSP Spinal Fixation System as cleared under K944736 and to the Harrington System manufactured by Zimmer in the early 1960s.

5. *Description of the Device:*

The ***CLARIS PLATE SYSTEM*** is a construct made of components that consists of pedicle and sacral screws, spine plates, nuts and connectors.

Claris Plate System Screws:
The screws of the Claris plate System are the "R" type screws of the ***SCS Claris Spinal System*** previously cleared under **K994288** (for the 5mm diameter) and **K983353** (for diameters of 6, 7, 8 and 9 mm).
The screws are made of grade titanium alloy conforming to ASTM F-136 specifications.
They exists in length from 25 mm to 60mm with 5mm increment.
The product code is identical to the SCS Claris spinal System product code in which "xx" represents the length of the screw and "2T10" represents the reference for titanium products.

The following table summarizes the diameters and item reference number of the SCS Claris screw:

Pedicle Sacral Screw Diameters	Item Reference
5mm	2T10-F5xx
6mm	2T10-F6xx
7mm	2T10-F7xx
8mm	2T10-F8xx
9mm	2T10-F9xx

Claris Plates:
The plates exist in length ranging from 40mm to 260mm with 10mm increment from 40mm to 100mm and then with 20mm size increment from 100mm on. The Claris Plate are made of CP titanium (a.k.a. T40) conforming to ASTM F 67 specifications.

The following table lists the different sizes of the Plate components for the Claris Plate System:

Item Reference	Length in mm
4T40-P040	40
4T40-P050	50
4T40-P060	60
4T40-P070	70
4T40-P080	80
4T40-P090	90
4T40-P100	100
4T40-P120	120
4T40-P140	140
4T40-P160	160
4T40-P180	180
4T40-P200	200
4T40-P220	220
4T40-P240	240

The Claris Plate System Locking Nut
Exists in one size only; it is manufactured from titanium alloy TA6V ELI conforming to ASTM F 136 specifications. The Claris Plate System Locking Nut has a 7mm Hex Shape head and a surface contact of 10.50 mm on the plate to insure fixation and prevent sliding.

The Claris Plate System Clamp or Plate Connector.
Made of titanium alloy TA6V ELI conforming to ASTM F 136 specifications, it is used to connect the screw to the plate and to prevent its spreading. The connector is placed on the screw to receive the Claris Plate before its locking with the Locking Nut.
The Claris Plate Connector exists in one size only.

6. **Applicant Name & Address:**
ORTHOTEC, LLC.
9595 Wilshire Blvd. Suite 502
Beverly Hills, CA 90212-4110
Tel: (310) 557-2000 & (310) 273-1500 ~ Fax:(310) 843-9500
email: Pbertranou@OrthoTec.net

7. Company Contact:

Patrick Bertranou M.D.
Regulatory Affairs
ORTHOTEC, LLC.
9595 Wilshire Blvd. Suite 502
Beverly Hills, CA 90212-4110
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8. Submission Correspondent:

Patrick Bertranou M.D.
ORTHOTEC, LLC.
9595 Wilshire Blvd. Suite 502
Beverly Hills, CA 90212-4110
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email: Pbertranou@OrthoTec.net

9. Performance Standards:

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations. **ORTHOTEC, LLC.** also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. Special Controls:

Special controls were published in the Federal Register, Vol. 63, No. 143, July 27, 1998 (Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems). The following special controls apply to the marketing of this device when used as a posterior pedicle system:

(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatability standard, and
(iv) Compliance with specified labeling requirements.

11. Special Guidance Document Information:

The 510(k) was prepared in accordance with:
"Guidance for Spinal System 510(k)'s" May 7, 1999.

12. Storage, Packaging & Sterilization Information:

The ***SCS Claris Plate System*** is supplied ***"NON-STERILE"*** and must be sterilized prior to use. The recommended sterilization process is high temperature steam autoclave sterilization. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated cycle is:

Method:	Steam
Cycle:	Gravity
Temperature:	250°F (121°C)
Exposure Time:	30 minutes

All packages containing implants or instruments should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the package or product is damaged, the product should not be used and should be returned.

Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

13. Comparison Table:

FEATURE	*Claris Plate System*		SE?
Indications for Use:	The Claris Plate System is a posterior, non pedicle system of the non cervical spine is indicated for patients with degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies spondylolisthesis,fracture spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis) tumors, failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine (T1-Sacrum) fixation only. In addition, the Claris Plate System is a posterior pedicle system indicated for the treatment of patients having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint in skeletally mature patients receiving fusion using autogenous bone graft only having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum) and intended to be removed after the development of a solid fusion mass. Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, failed previous fusion (pseudarthrosis)	SAME	YES
Design:	Cancellous thread pedicle screw, sacral screws, plates, nuts	SAME	YES
Sterile:	Non-sterile	SAME	YES
Sizes:	From 5.0mm to 9.5 diameter, 25mm through 60mm lengths	SAME	YES
Material:	titanium alloy, CP titanium	SAME	YES
Manufacturer:	OrthoTec, LLC.	SAME	YES
Product Code:	KWP MNH MNI	SAME	YES
K - Number:	Pending	**K944736**	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Patrick Bertranou, M.D.
President
OrthoTec, L.L.C.
546 Hillgreen Drive
Beverly Hills, California 90212-4110

Re: K010369
Trade Name: Claris Plating System
Regulation Number: 888.3070 and 888.3060
Regulatory Class: II
Product Code: MNH, MNI and KWP
Dated: February 5, 2001
Received: February 7, 2001

Dear Dr. Bertranou:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K010369

Device Name: *Claris Plate System*

Indications For Use:

Intended Use(s) of the Device:

The Claris Plate System is a posterior, non pedicle system of the non cervical spine is indicated for patients with:

degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
spondylolisthesis
fracture
spinal stenosis
deformities (i.e., scoliosis, kyphosis, lordosis)
tumors
failed previous fusion (pseudarthrosis)

Levels of fixation are for the thoracic, lumbar and sacral spine (T1-Sacrum) fixation only.

In addition, the Claris Plate System is a posterior pedicle system indicated for the treatment of patients:

having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint in skeletally mature patients receiving fusion using autogenous bone graft only having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum) and intended to be removed after the development of a solid fusion mass.

Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

degenerative spondylolisthesis with objective evidence of neurologic impairment
fracture
dislocation
scoliosis
kyphosis
failed previous fusion (pseudarthrosis)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010369

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ *OR* *Over-The-Counter Use* _____
(Per 21 CFR 801.109) *(Optional format 1-2-96)*